510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

OCT 2 3 2012

A. Submitted by:

Sheila Bruschi
Associate Manager, Regulatory Affairs
NuVasive, Incorporated
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San Diego, California 92121
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Date Prepared: August 24, 2012

B. Device Name

Trade or Proprietary Name:	*Sage® Lateral Plate System*
Common or Usual Name:	Spinal Implants
Classification Name:	Spinal Intervertebral Body Fixation orthosis
Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	KWQ

C. Predicate Devices

The subject *Sage Lateral Plate System* is substantially equivalent to the following predicate devices: *NuVasive® Lateral Plate System (*K061789*), NuVasive Anterior Lumbar Plate* (K072339) and *Synthes Antegra-T System (*K081568*).*

D. Device Description

The *NuVasive Sage Lateral Plate System* is an anterior/anterolateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). The *Sage Lateral Plate System* includes plates, screws, and spikes manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or ISO 5832-3, as well as associated manual general surgical instruments. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

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E. Intended Use

The *NuVasive Sage Lateral Plate System* is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

F. Technological Characteristics

As was established in this submission, the subject *Sage Lateral Plate System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject *Sage Lateral Plate System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic compression testing per ASTM F1717
- Static torsion testing per ASTM F1717

The results demonstrate that the subject *Sage Lateral Plate System* presents no new worst-case for performance testing, and the subject device was therefore found to be substantially equivalent to the predicate.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *Sage Lateral Plate System* has been shown to be substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NuVasive, Incorporated
% Ms. Sheila Bruschi
Associate Manager, Regulatory Affairs
7475 Lusk Boulevard
San Diego, California 92121

OCT 23 2012

Re: K121815
Trade/Device Name: NuVasive® Sage® Lateral Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 16, 2012
Received: October 17, 2012

Dear Ms. Bruschi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121815

Indications for Use

510(k) Number (if known): K121815

Device Name: NuVasive® Sage® Lateral Plate System

Indications For Use:

The *NuVasive Sage Lateral Plate System* is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121815

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